PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 25/00 — A3

(11) International Publication Number: WO 99/17827

(43) International Publication Date: 15 April 1999 (15.04.99)

(21) International Application Number: PCT/US98/20800

(22) International Filing Date: 2 October 1998 (02.10.98)

(30) Priority Data:
08/943,628 3 October 1997 (03.10.97) US

(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One SciMed Place, Maple Grove, MN 55311-1566 (US).

(72) Inventors: LANGE, Michael, R.; 1415 Wynne Avenue, St. Paul, MN 55108 (US). PEPIN, Henry, J.; 4115 Townline Road, Loretto, MN 55357 (US).

(74) Agents: CROMPTON, David, M. et al.; Crompton, Seager & Tufte, LLC, Suite 895, 331 Second Avenue South, Minneapolis, MN 55401-2246 (US).

(81) Designated States: CA, JP, MX, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(88) Date of publication of the international search report:
8 July 1999 (08.07.99)

(54) Title: BRAIDED ANGIOGRAPHY CATHETER HAVING FULL LENGTH RADIOPACITY AND CONTROLLED FLEXIBILITY

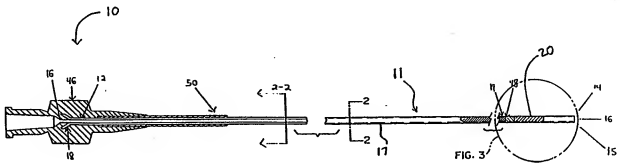


FIG. 3

(57) Abstract

A guiding catheter or angiographic catheter for use in cardiovascular interventions which incorporates a low-flexibility multi-layer proximal zone wherein a transition zone separates the proximal zone and a high flexibility distal zone. A mid-region zone transitions the high stiffness of the proximal zone to the higher flexibility of the distal zone to eliminate buckling and kinking. All zones of the catheter have a sufficiently large and substantially similar radiopacity, which allows the entirety of the catheter to be visible in a fluoroscope or other form of X-ray so that the positioning of the catheter can be precisely determined.

BRAIDED ANGIOGRAPHY CATHETER HAVING FULL LENGTH RADIOPACITY AND CONTROLLED FLEXIBILITY

Technical Field

This invention relates to the field of intravascular medical devices, and more particularly, to the field of catheters such as angiographic and guide catheters used for the placement of medicines and medical devices within the body. Specifically, the invention is directed to an improved guide or diagnostic catheter having full length radiopacity incorporating a proximal zone having lower flexibility than a distal zone, where a transition zone provides varying flexibility between the proximal zone and the distal zone for improved catheter performance.

Background of the Invention

Angiographic and guide catheters are well known in the field of medicine for use in conjunction with other catheters for the treatment of cardiovascular disease through such procedures as percutaneous transluminal coronary angioplasty (PTCA) procedures. Guide catheters aid in treatment of arterial lesions by providing a conduit for positioning dilatation balloon systems across an arterial stenosis. The need for a greater variety of guide catheters to treat different types of circumstances has grown tremendously as the techniques for the use of such devices has grown.

During the treatment of cardiovascular disease, the catheter must be able to traverse tortuous pathways through blood vessels in a manner that minimizes trauma. In order for the physician to place the catheter at the correct location in the vessel, the physician must apply longitudinal and rotational forces. The catheter must be stiff enough to resist the formation of kinks, while at the same time, the catheter must possess flexibility to be responsive to maneuvering forces when guiding the catheter through the vascular system. The catheter must be rigid enough to push through the blood vessel, but yet flexible enough to navigate the bends in the blood vessel. The guide or angiographic catheter must exhibit good torque control such that manipulation of a proximal portion of the catheter is responsively translated to the tip or distal end of the catheter to curve and guide the catheter through the tortuous pathways. Thus, the catheter must have torsional rigidity to transmit the applied torque. To accomplish this balance between

transition section in which the materials of the stiff and flexible sections are joined into each other in a smooth gradual manner to produce an inseparable bond between the materials without abrupt joints. This tubing is manufactured using an extrusion process and may be limited in its ability to manufacture catheters having the desired number of regions of varying stiffness and the ability to easily accommodate product design changes during manufacture.

Catheters may be manufactured using this approach, but its practical application may be limited to joining two materials to form two zones of flexibility with a transition therebetween. Thus, with this approach, additional manufacturing steps are necessary to provide for additional regions. These regions of varying stiffness are necessary to provide rigidity to push the catheter through the blood vessel, flexibility to navigate the bends in the blood vessel, and torsional stiffness to correctly place the catheter by maintaining torque control without excessive energy storage which can cause undesirable movement of the catheter end.

It is advantageous that the catheter be visible in a fluoroscope or other form of x-ray, so that the catheter can be positioned with precision. In the prior art, this has been accomplished by applying a metal ring to the catheter adjacent the distal end. It is generally undesirable to place the metal ring exactly on the distal tip of the catheter, since the distal tip needs to be very soft and pliable. Therefore, the metal ring does not completely resolve the problem of precisely locating the distal tip of the catheter within the body by means of a fluoroscope during a medical procedure, since the metal ring is and must be spaced from the distal tip. In other prior art, the distal tip has been manufactured to be substantially more radiopaque than portions of the catheter proximal to the tip.

Summary of the Invention

The present invention overcomes many of the disadvantages found in the prior art by providing a guiding catheter for use in coronary angioplasty and other cardiovascular interventions which incorporates a lower flexibility proximal shaft portion, coupled to a higher flexibility distal tip portion. Within the distal tip, there are three distinct zones of flexibility. A tip transition portion separates a proximal tip portion

Brief Description of the Drawings

Other objects of the present invention and many of the attendant advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, in which like reference numerals designate like parts throughout the figures thereof and wherein:

Fig. 1 is a plan view with the manifold cross sectioned of a catheter showing a preferred embodiment of the present invention;

Fig. 2 is a cross section view of Fig. 1 taken along line 2-2;

Fig. 3 is a plan view of the distal tip area of the catheter of Fig. 1, illustrating the shaft/tip heat bonding site and the portions of the distal tip including a transition zone of varying stiffness.

Detailed Description of the Preferred Embodiments

Referring now to the drawings, wherein like reference numerals refer to like elements throughout the several views, Fig. 1 is a plan view of a catheter with the manifold shown in cross section showing a preferred embodiment of the present invention. Figure 1 shows a catheter 10 which comprises a hub 46, and a linear shaft 11 having a proximal end 12 and a distal end 14. A central lumen 16 extends longitudinally through the linear shaft from the proximal end 12 to the distal end 14. The linear shaft 11 comprises a proximal shaft 17 and a distal tip 20. The proximal shaft 17 has a proximal end 18 and a distal end 19. The distal tip 20 is attached to the distal end 19 of the proximal shaft 17 at the shaft/tip heat bonding site 48.

Referring now to Fig. 2, the proximal shaft portion 17 includes an inner tubular member 22 formed from polyurethane which extends from the proximal end 18 to the distal end 19 of the proximal shaft 17. The inner tubular member 22 defines the inner diameter 21 of the central lumen 16. An intermediate tubular member of polyether block amide copolymer (PEBA) 24, commercially available under the trademark PEBAX, is extruded over the entire length of the inner tubular member 22. The intermediate tubular member of PEBAX 24, has a durometer of 67D, is 80% loaded with a Tungsten filler and a 1% UV stabilizer.

The proximal portion 38 of the distal tip 20 has a durometer of 70 D, and is 55% loaded with a Tungsten filler and a 1% UV stabilizer. The distal portion 42 has a durometer of 47 D, and is also 55% loaded with a Tungsten filler and a 1% UV stabilizer. The transition portion 40 has a durometer ranging from 70 D at the proximal end 43 to 47 D at the distal end 44, as provided by the ILC process. Experiments show that the proximal shaft portion 17 has substantially the same radiopacity as the distal tip 20.

Referring back to Fig. 1, the proximal end 18 of the proximal shaft portion 17 extends into a hub 46 molded directly over the proximal shaft portion 17. A 63 D white PEBAX strain relief is insert molded to the hub, and the proximal shaft portion 17 extends into the hub 46 through the PEBAX strain relief 50.

Having thus described the preferred embodiments of the present invention, those of skill in the art will readily appreciate that yet other embodiments may be made and used within the scope of the claims hereto attached.

6. The tubular assembly of claim 1 wherein said intermediate tubular member is substantially cooled before said woven braid member is provided so that said woven braid is not embedded in outer surface of said intermediate tubular member.

7. The tubular assembly of claim 1 wherein said outer tubular member is formed of polyether block amide having a durometer of 67 D, is 80% loaded with a Tungsten filler and a 1% UV stabilizer.

8. The tubular assembly of claim 1 wherein said outer sleeve tubular member substantially overlies all of said outer tubular member and conforming thereto.

9. The tubular assembly of claim 1 wherein said outer sleeve tubular member is formed from polyether block amide having a durometer of 70D, and is 30% loaded with a bismuth subcarbonate filler and 1% colorant (phthalocyanine blue, violet 23).

10. A tubular assembly for an intravascular catheter comprising:

a linear shaft having a proximal end, a distal end, and a lumen extending longitudinally therethrough;

a proximal shaft portion of high radiopacity included within said linear shaft, said proximal shaft portion extending distally a predefined distance from the proximal end of said linear shaft, wherein said proximal shaft portion has a proximal end and a distal end; and

a distal tip, said distal tip having a lumen therethrough, said distal tip included within said linear shaft portion extending distally from the distal end of said proximal shaft portion to the distal end of said linear shaft so that said lumen of said proximal shaft portion and said lumen of said distal tip form a continuous lumen extending from said proximal end of said proximal shaft portion through a distal end of said distal tip, said distal tip further comprising a proximal portion having a first material of a first stiffness, a transition portion having a second material with a continuous differential second

17. The tubular member of claim 10 wherein substantially all portions of said proximal shaft and said distal tip have substantially similar radiopacity.

18. The tubular assembly of claim 11 wherein the inner tubular member is formed from polyurethane.

19. The tubular assembly of claim 11 wherein the intermediate tubular member is formed of polyether block amide, having a durometer of 67 D, loaded with a Tungsten filler and/or UV stabilizer.

20. The tubular assembly of claim 11 wherein the woven braid member is braided from strands of stainless steel.

21. The tubular assembly of claim 11 wherein said woven braid is embedded in outer surface of said intermediate tubular member.

22. The tubular assembly of claim 11 wherein said intermediate tubular member is substantially cooled before said woven braid member is provided so that said woven braid is not embedded in outer surface of said intermediate tubular member.

23. The tubular assembly of claim 11 further comprising:

an outer tubular member contained within said proximal shaft portion substantially overlying said woven braid member and conforming thereto.

24. The tubular assembly of claim 23 wherein said outer tubular member is formed of polyether block amide having a durometer of 67 D, is 80% loaded with a Tungsten filler and a 1% UV stabilizer.

25. The tubular assembly of claim 24 further comprising:

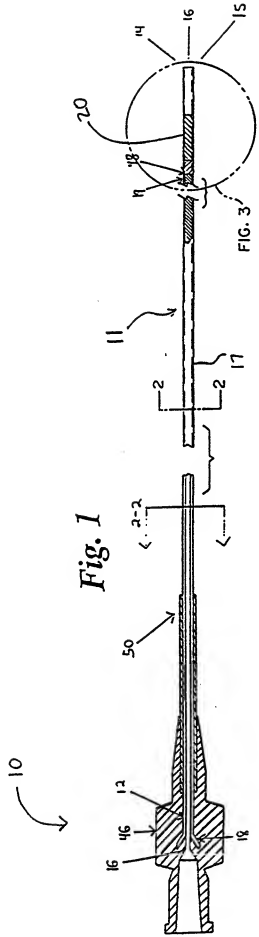


Fig. 1

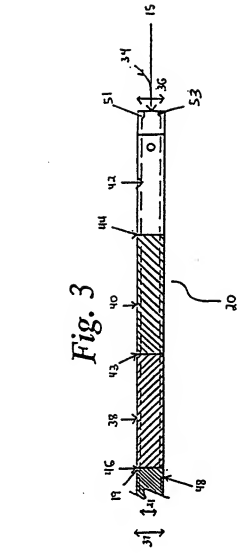


Fig. 3

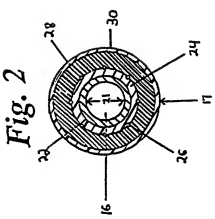


Fig. 2

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 970 715 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
12.01.2000 Bulletin 2000/02

(51) Int Cl.7: **A61M 25/00**

(21) Application number: **99305130.9**

(22) Date of filing: **29.06.1999**

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **30.06.1998 US 106966**

(71) Applicant: **Cordis Corporation**
Miami Lakes Florida 33014 (US)

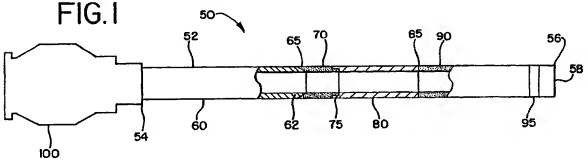
(72) Inventors:
- **Martinez, Susana M.**
  Coral Gables, Florida 33134 (US)
- **Shkolnik, Boris**
  Aventura, Florida 33160 (US)

(74) Representative: **Mercer, Christopher Paul**
Carpmaels & Ransford
43, Bloomsbury Square
London WC1A 2RA (GB)

(54) Flow directed catheter having radiopaque strain relief segment

(57) A flow directed catheter for use in medical diagnostic or therapeutic procedures having a strain relief segment between the relatively stiff proximal section of the catheter and the floppy distal tip portion in which the strain relief segment is formed of a polymeric material containing a radiopaque agent.

FIG. 1



EP 0 970 715 A2

Description

Field of the Invention

[0001] A flow directed catheter for use in medical diagnostic or therapeutic procedures having a strain relief segment between the relatively stiff proximal section of the catheter and the floppy distal tip portion in which the strain relief segment is formed of a polymeric material containing a radiopaque agent.

Background Art

[0002] In order to diagnose the extent of coronary artery disease angiography procedures are used to view the blood flow through selected blood vessels. In carrying out this procedure diagnostic catheters are introduced into the blood vessels of a patient and are advanced over a guidewire through the vascular system of the patient until the distal end of the catheter is steered into the particular blood vessel to be examined.

[0003] In view of the fact that the human vasculature is quite tortuous it is essential that a diagnostic catheter be capable of being steered by torquing the proximal hub of the catheter in order to direct the catheter through the vascular system. With extremely small vessels it is often not possible to provide a catheter with sufficient flexibility for passage through the tortuous vasculature while still providing sufficient rigidity to steer, or torque, the distal end of the catheter to a desired site. Accordingly, in certain instances it is desirable to provide a catheter in which the proximal end of the catheter is relatively stiff and the distal end of the catheter is very flexible, or floppy, in order that the distal tip of the catheter may be steered, or directed, through the vasculature by means of the flow of blood through the vessel. Such catheters are generally referred to as flow directed catheters.

[0004] Such flow directed catheters generally comprise a connector hub, a relatively long and stiff proximal section for pushing the catheter into the vasculature system, and a shorter and very floppy distal tip section. The floppy distal tip section is of a very low durometer in order that the tip section may be guided, or directed, by the flow of blood through the blood vessel.

[0005] Medical catheters have for many years included a relatively short distal tip which is formed of a polymeric material containing a radiopaque agent in order that the distal tip of the catheter may be readily viewed under X-ray radiation as the catheter is passed through the blood vessels of a human body. With a radiopaque distal tip it is possible for the physician to observe the exact location of the distal tip portion of the catheter relative to its position within the human body.

[0006] Examples of prior art patents which disclose medical catheters having distal tips containing a radiopaque agent are United States Patent No. 5,045,072 entitled "Catheter Having Highly Radiopaque, Flexible Tip" to Castillo et al. and United States Patent No. 5,171,232 to entitled "Catheter Having Highly Radiopaque, Flexible Tip" Castillo et al., both of which are assigned to the assignee of the present application and are incorporated herein by reference

[0007] One problem with currently available flow directed catheters is that with these devices the physician is unable to determine the exact position of the transition area between the relatively stiff proximal portion of the catheter and the floppy distal portion of the catheter. With the inability to determine the location of this transition area it is very difficult to determine which portion of the catheter may be steered by torquing on the hub of the catheter and which portion of the catheter may not be so steered but may simply be permitted to be directed by the flow of blood through the blood vessel. In addition, it is difficult for the doctor to prevent kinking of the relatively soft floppy portion of the catheter as this portion of the catheter passes through the blood vessel if the doctor is unable to discern whether a particular portion of the catheter is formed of a relatively stiff material or a very floppy material.

Summary of the Invention

[0008] The present invention relates to a flow directed catheter intended for the insertion into the blood vessels of a patient which may be guided through the vasculature of the patient by a force exerted on the floppy distal portion of the catheter by the flow of blood through the vasculature. The catheter includes a strain relief section which is positioned between a relatively rigid proximal portion of the catheter and a floppy distal portion of the catheter and in which the strain relief section is formed of a polymeric material containing a radiopaque agent with this device, the physician may readily determine the exact position of the strain relief portion of the catheter or the position of the transition region between the relatively stiff portion of the catheter and the very floppy distal portion of the catheter.

[0009] Flow directed catheters constructed in accordance with the present invention include a proximal connector hub, a relatively stiff proximal tubular section bonded to the hub, a highly flexible distal tubular section, and a relatively short tubular strain relief section interposed between the proximal tubular section and the distal top section. The tubular strain relief section is more flexible than the proximate tubular section and less flexible than the distal tubular section and is formed of a polymeric material containing a radiopaque agent. With this device, a physician is able to precisely locate the position of the strain relief section of the catheter. The highly flexible tubular section is very floppy in nature and its position is controlled by the flow of blood through the blood vessel to thereby permit the physician to precisely position the distal tip of the catheter at a desired site.

[0010] In accordance with another aspect of the present invention, the tubular strain relief section is formed of a polymeric material containing from about 40

to 75 weight percent of radiopaque agent, such as barium sulfate, bismuth subcarbonate or bismuth trioxide.

[0011] In accordance with still another aspect of the present invention, the tubular strain relief section is thermally fused to the distal end of the proximal tubular section and the distal tubular section is thermally fused to the distal end of the strain relief section. In addition, the tubular strain relief section is preferably free of any metallic radiopaque member, such as a metal ring, which is positioned on or adjacent to the strain relief section.

[0012] In accordance with another aspect of the present invention, the highly flexible distal section, or floppy distal tip, is more than twenty times the length of the strain of the relief section and the relatively stiff proximal section of the catheter is more than ten times the length of the floppy distal section. In addition, the proximal tubular section preferably has a durometer of between 60D and 90D, the strain relief section has a durometer of between 25D and 50D and the distal tubular section has a durometer between 50A and 90A.

[0013] In accordance with still another aspect of the present invention, the distal floppy section has a length of between 10 and 50 centimeters and may be comprised of an inner distal section and an outer distal section in which the inner distal section is more flexible than the strain relief section of the catheter and the outer distal section is more flexible than the inner distal section.

[0014] From the above it may be appreciated that one object of the invention is a flow directed catheter with a floppy distal tip which may be directed through the vasculature by the flow of blood and in which a radiopaque strain relief section is positioned between the floppy distal tip and a relatively stiff proximal section to thereby provide the physician with an exact location of the transition area between the relatively stiff proximal section and the floppy distal tip of the catheter. This and other objects, advantages and features of the invention will become better understood from a detailed description of the invention which is described in conjunction with the accompanying drawings:

BRIEF DESCRIPTION OF THE DRAWINGS

[0015]

Figure 1 is a partially crossed-sectional view of the flow directed catheter of the present invention which illustrates the various section of the catheter;

Figure 2 is a partially crossed-sectional view of a flushable stilt for use with the flow directed catheter of Figure 1;

Figure 3 is an elevational view of the flow directed catheter of Figure 1 in conjunction with the flushable stylet of Figure 2; and,

Figure 4 is diagrammatic view showing the flow directed catheter of the present invention inserted in the tortuous vasculature of a human body.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

[0016] Figure 1 illustrates the assembled flow directed catheter 50 having a main tubular body 52 with a proximal end 54 and a distal end 56 and an inner lumen 58 extending there through. The main tubular body 52 is constructed from four segments; a relatively stiff proximal shaft segment 60, a radiopaque strain relief segment 70, a proximal floppy segment 80 and a soft distal floppy segment 90.

[0017] The relatively stiff proximal shaft segment 60 of main tubular body 52 is preferably made from a high durometer polymeric material or a polymer coated metallic hypotube. Suitable polymers for the proximal shaft segment 60 include biologically compatible polymers such as nylon, polyethylene, polyester, polyurethane, silicone and the like. The durometer of the proximal shaft segment 60 is between 60D and 90D and is preferably 75D. The proximal shaft segment 60 provides proximal support for flow directed catheter 50, enabling pushability without the need of a guidewire. The proximal shaft segment 60 comprises a proximal end 54 to which a hub coupling 100 is attached and a slight distal taper 62 to which the radiopaque strain relief segment 70 is attached. The length of proximal shaft segment 60 is between 100 cm and 145 cm preferably between 125 cm and 130 cm. The preferable inner diameter and outer diameter of proximal shaft segment 60 are about 0.55 mm and 0.94 mm respectively. The length of the slight distal taper 62 is between 0.1 mm and 3 mm more preferably between 1.5 mm and 2.5 mm.

[0018] The proximal shaft segment 60 is attached to the radiopaque strain relief segment 70 at the slight distal taper 62 by a thermal fuse joint 65. The thermal fuse joint 65 is created by placing the slight distal taper 62 of proximal shaft segment 60, while on a mandrel, inside of the radiopaque strain relief segment 70 and heating the assembly. Depending upon the materials used for the proximal shaft segment 60 and the radiopaque strain relief segment 70 the fusing temperature ranges from 300°F to 550°F. Preferably the fuse temperature is between 350°F and 450°F.

[0019] The radiopaque strain relief segment 70 provides the physician with a visible marker under fluoroscopy indicating the location of the relatively stiff proximal shaft segment 60 in relation to the guiding catheter tip. The radiopaque strain relief segment 70 also prevents kinking that occurs when a rigid tube is connected to a very flexible tube. The radiopaque strain relief segment 70 is more flexible than the proximal shaft segment 60 and made from a polymer tube that has been made radiopaque by incorporating radiopaque fillers during the forming process. The strain relief segment 60 is of a durometer of between about 25D and 50D and is preferably about 40D. Suitable fillers include powders made from metals such as tungsten and tantalum as well as compounds containing barium and bismuth such as bar-

ium sulfate, bismuth subcarbonate and bismuth trioxide. Preferably the strain relief segment 60 is formed of a polymeric material containing between 40 and 75 weight percent of the radiopaque agent. Since the incorporation of fillers generally increase the stiffness of a polymer the length of the radiopaque strain relief segment 70 must be fairly small, between 0.4 cm and 0.6 cm preferably about 0.5cm.

[0020] The radiopaque strain relief segment 70 is attached to a proximal floppy segment 80 by a thermal fuse joint 75. The proximal floppy segment 80 is more flexible, i.e. lower durometer than the radiopaque strain relief segment 70 and proximal shaft segment 60. The inner diameter of the radiopaque strain relief segment 70 and the proximal floppy segment 80 is between 0.25 mm and 0.55 mm preferably about 0.42 mm, while the outer diameter is between 0.60 mm and 0.94 mm preferably about 0.79 mm. The length of the proximal floppy segment 80 is between 10 cm and 20 cm preferably about 15 cm.

[0021] The proximal floppy segment 80 is attached to the distal floppy segment 90 by a thermal fuse joint 85. The distal floppy segment 90 is constructed from a low durometer polymer and is more flexible than the proximal floppy segmentile the outer diameter is between 0.25 mm and 0.76 mm preferably 0.61 mm. The length of the distal floppy segment is between 10 cm and 30 cm preferably about 20 cm. To make the distal tip of flow directed catheter 50 visible under fluoroscopy a radiopaque marker 95 is attached to distal floppy segment 90. To facilitate access to some vessels in tortuous anatomy the distal tip of the distal floppy segment 90 may be preshaped. The proximal floppy segment 80 is of a durometer between about 50A and 90A and preferably between about 70A and 80A. The distal floppy segment 90 is of a durometer of between about 50A and 90A and is preferably between about 65A and 75A.

[0022] To reduce damage while using, the flow directed catheter 50 is coated with a lubricious polymer. This coating may be hydrophobic or hydrophilic in nature, preferably hydrophilic, and applied to the interior and exterior of flow directed catheter 50. Hydrophilic coatings are widely known in the industry and may be applied using a dip coating process and subsequently dried, covalently bonded and crosslinked using a single thermal drying cycle. Preferably this drying temperature would be below the softening point of the polymers being coated about 50°C to 60°C. To facilitate the introduction of flow directed catheter 50 into the guiding catheter a stylet is inserted to provide support.

[0023] Figure. 2 illustrates a flushable stylet 250 for use with flow directed catheter 50. The flushable stylet 250 allows the hydrophilic coating on the interior of flow directed catheter 50 to be flushed and hydrated without removing the stylet. This procedure prevents damage to the interior coating of the flow directed catheter 50. Flushable stylet 250 consists of a hollow tube body 252, with a proximal end 254 to which a luer hub 290 is attached and having a distal end 256. The proximal end 254 of the tube body 252 is attached to luer hub 290 by using an adhesive or thermal fuse with the lumen of luer hub 290 remaining open. The tube body 252 may be coated with a hydrophobic or hydrophilic lubricious polymer, preferably hydrophobic. To facilitate introduction of the flushable stylet 250 into flow directed catheter 50, the tube body 252 may also be tapered.

[0024] Figure 3 illustrates the catheter sytlet assembly 300. The flushable stylet 250 is placed inside of flow directed catheter 50 coaxially. Luer hub 290, secures onto hub coupling 100. A syringe filled with saline attaches to luer hub 290 and saline is infused through luer hub 290 and into flow directed catheter 50.

[0025] Figure 4 illustrates the flow directed catheter 50 inserted into the vasculature 400. Guiding catheter 30 is located in the vascular territory 400 proximal to the intended embolization site 480. In general the intended embolization site 480 is a region of relatively high flow as associated with an arteriovenous malformation or fistula. Flow directed catheter 50 is extended from the guiding catheter 30 and traverses the vasculature 400 towards the intended embolization site 480. Once the intended embolization site 480 is reached various types of therapeutic agents such as platinum coils, polyvinylalcohol particles, ethanol or cyanoacrylate adhesives may be delivered to treat the lesion. For regions of low flow, flow directed catheter 50 may be used in conjunction with a guidewire inserted in the lumen to access lesions.

Those skilled in the art will appreciate that the flow directed catheter of the present invention may be manufactured from various materials and with various durometers to suit the desires of different physicians.

[0026] Various modification and changes in detail may be made to the above-described embodiments and examples without departing from the spirit and scope of the invention. It is therefore intended that all such matter as described in the foregoing description and shown in the attached drawings be considered as illustrative only and not limiting.

Claims

1. A flow directed catheter comprising a proximal connector hub, a relatively stiff proximal tubular section bonded to the hub, a highly flexible distal tubular section and a relatively short tubular strain relief section interposed between the proximal tubular section and the distal tip section, said tubular strain relief section being more flexible than the proximal tubular section and less flexible than the distal tubular section and being formed of a polymeric material containing a radiopaque agent.

2. The flow directed catheter as defined in Claim 1, wherein the tubular strain relief section is formed of

a polymeric material containing from 40 to 75 weight percent of a radiopaque agent.

3. The flow directed catheter as defined in Claim 1, wherein the tubular strain relief section is thermally fused to the distal end of the proximal tubular section and the distal tubular section is thermally fused to the distal end of the tubular strain relief section.

4. The flow directed catheter as defined in Claim 1, wherein the highly flexible distal section is more than twenty times the length of the strain relief section and the relatively stiff proximal section is more than 10 times the length of the highly flexible distal section.

5. The flow directed catheter as defined in Claim 3, wherein the proximal tubular section has durometer of between 60D and 90D, the strain relief section has a durometer of between 25D and 50D and the distal tubular section has a durometer of between 50A and 90A.

6. The flow directed catheter as defined in Claim 5, wherein the distal tubular section has a length of between 10 and 50 centimeters.

7. The flow directed catheter as defined in Claim 6, wherein the distal tubular section is comprised of a proximal segment and a distal segment and the proximal segment is more flexible than the strain relief section and the distal segment is more flexible than the proximal segment.

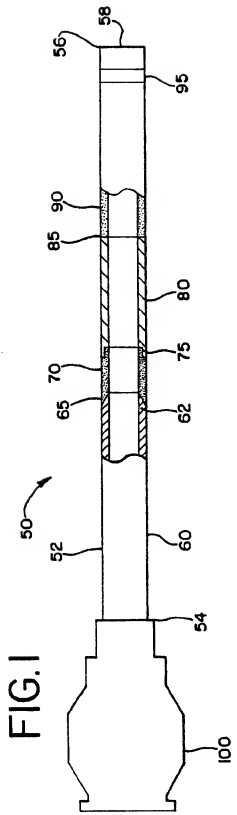


FIG.1

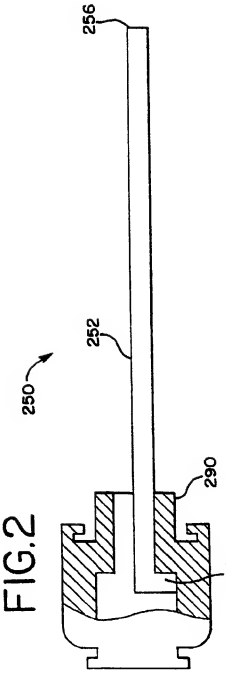


FIG.2

FIG.4

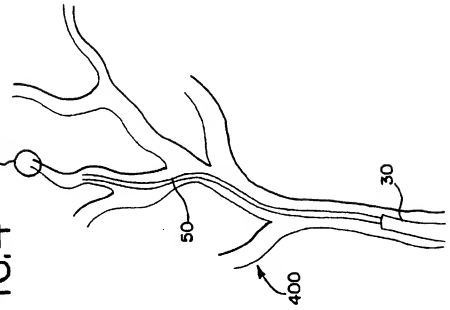
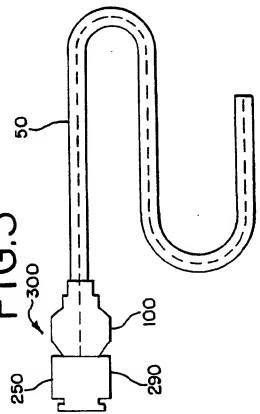


FIG.3



Europäisches Patentamt
European Patent Office
Office européen des brevets

European Patent Office
80298 MUNICH
GERMANY
Tel: +49 89 2399 0
Fax: +49 89 2399 4465

Jennings, Nigel Robin
KILBURN & STRODE
20 Red Lion Street
London WC1R 4PJ
ROYAUME-UNI

006155

Formalities Officer
Name: Etöndi, Jo-Anne
Tel: +49 89 2399 - 6043
or call
+31 (0)70 340 45 00

Substantive Examiner
Name: Türkavci, Levent
Tel: +49 89 2399 - 8142

COPY

Application No. 03 796 822.9 - 2310	Ref. NRJ/P38940EP-K	Date 10.06.2008
Applicant AngioDynamics, Inc.		

Communication pursuant to Article 94(3) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).

Europäisches Patentamt · European Patent Office · Office européen des brevets

K+S Received	
Entered:	
Date:	16 JUN 2008
Checked:	
F/E	

Türkavci, Levent
Primary Examiner
for the Examining Division

Registered Letter
EPO Form 2001 12.07CSX

Europäisches Patentamt
European Patent Office
Office européen des brevets

European Patent Office
80298 MUNICH
GERMANY
Tel: +49 89 2399 0
Fax: +49 89 2399 4465

Enclosure(s): 5 page/s reasons (Form 2906)

The examination is being carried out on the **following application documents:**

Description, Pages

1-16 as published

Claims, Numbers

1-16 received on 28.06.2005 with letter of 27.06.2005

Drawings, Sheets

1/3-3/3 as published

1. Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure:

   D1: US-A-5 045 072 (CASTILLO MIGUEL A [US] ET AL) 3 September 1991 (1991-09-03)

   D2: WO 99/17827 A (SCIMED LIFE SYSTEMS INC [US]) 15 April 1999 (1999-04-15)

2. The application comprises 2 independent apparatus claims (1 and 10).

   Although these claims have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.
   Hence, the above claims are not allowable since they do not meet the requirements

of Article 84 EPC.

In order to overcome this objection, it would appear appropriate to file an amended set of claims defining the relevant subject-matter in terms of a single independent claim followed by dependent claims (Rules 43(2) to (4) EPC).

3. INDEPENDENT CLAIM 1

The present application, notwithstanding the above-mentioned lack of clarity, does not meet the requirements of Article 52(1) EPC, because the subject-matter of claim 1 is not new in the sense of Article 54(1) and (2) EPC.

The document D1 being the closest prior art discloses (the references in parentheses applying to this document):

A central venous catheter (col.3, line 3-5, fig.1,(10)) comprising:

a proximal tube segment (15) containing a polymer material of a first durometer and a first amount of a radiopaque filler (col.3 lines 41-51);
a distal tube segment (14) having a polymer material of a second durometer and a second amount of a radiopaque filler, wherein the first durometer is higher than the second durometer and the percentage by weight of the first amount is lower than that of the second amount (col.3, lines 30-40) ;
and a transition tube segment (13) interposed between the proximal tube segment and the distal tube segment (col.3, line 16 and fig.1).

Therefore the subject-matter of claim 1 is not new (Article 54(1) and (2) EPC).

4. INDEPENDENT CLAIM 10

4.1 The present application, notwithstanding the above-mentioned lack of clarity, does not meet the criteria of Article 52(1) EPC, because the subject matter of claim 1 does not involve an inventive step in the sense of Article (56) EPC.

4.1 Document D1, which is considered to represent the most relevant state of the art to the subject matter of claim 10, discloses (the references in parentheses applying to

this document):

A central venous catheter (col.3, line 3-5, fig.1,(10)) comprising:
a proximal tube segment (15) of a first durometer(col.3 lines 41-51);
a distal tube segment (14) of a second durometer that is lower than the first durometer (col.3, lines 30-40);
a transition lube segment interposed between the proximal tube segment and the distal tube segment (13),
the proximal, distal and transition tube segments together define a single integrally formed tube (fig.1)

4.2 The subject-matter of independent claim 18 differs from the disclosure of D1 in that the transition tube segment is continuously variable in durometer over the length of the transition tube segment. The effect is that the catheter shaft has an improved kinking or buckling resistance.

4.3 The problem to be solved by the present invention may therefore be regarded as how to improve the maneuverability of the catheter through traverse tortuous pathways of blood vessels.

4.4 In view of D2 the solution proposed in claim 10 of the present application cannot be considered as involving an inventive step (Article 56 EPC) for the following reasons: D2 discloses a transition portion (40) between a region with a material that has a higher stiffness (38) and another material that has a lower stiffness (42). This transition region is defined by a gradual stiffness transition along its path which eliminates buckling and kinking (page 4, lines 1-4 and 24-30) that results in an improved maneuverability of the catheter (implicit).

4.5 Therefore the features disclosed in D1 and D2 would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 10 thus cannot be considered inventive (Article 56 EPC).

5. DEPENDENT CLAIM 9

The feature of dependent claim 9 is also disclosed in D1 (see fig.1) and it is not

novel (Art. 54(1) and (2) EPC).

6. DEPENDENT CLAIMS 4-6,11,14 and 16

Dependent claims 4-6,11,14 and 16 do not contain any additional features which, in combination with the features of any claim they refer, meet the requirements of the EPC with respect to inventive step, the reasons being as follows:

7.1 D1 renders obvious in combination with the features of D2:
Claim 11 - "Less radiopaque filler in proximal part", (see claims 17,18)
Claim 16 - " Single tube", (fig.1)

7.2 D2 renders obvious in combination with the features of D1:

Claims 4,5,6,14 - "Continuously decreasing durometer", (page 4, lines 24-30, implicit and page 7, lines 4-6)

Therefore the features of claims 4-6,11,14 and 16 do not involve any inventive step (Articles 52(1) and 56 EPC).

8. DEPENDENT CLAIMS 2,3,7,8,12,13,15

The combination of the features of dependent claims 2,3,7,8,12,13 and 15 are neither known from, nor rendered obvious by, the available prior art.

9. The following amendments should also be considered:

9.1 At present, it cannot be anticipated which features the applicant desires to incorporate into claim 1, in order to arrive at matter meeting the requirements of the EPC.

9.2 The applicant is invited to file an amended set of claims overcoming the above objections.

9.3 Any new independent claim will have to be worded in the two-part form incorporating in its pre-characterising portion the features disclosed in D1 as the closest prior art and with the remaining features being included in the characterising part (Rule 43(1),EPC).

9.4 Reference signs should be used throughout the claims (Rule 43(7)).

9.5 To meet the requirements of Rule 42(1)(b) EPC, the document D1 should be identified in the description and the relevant background art disclosed therein should be briefly discussed.

9.6 In order to be able to assess the question of inventive step, the applicant is asked to indicate in the response which technical problem is solved by the characterising features of the new claim 1 compared to D1 as the closest prior art (Rule 42(1)c)EPC).

9.7 The description will have to be brought into line with the new claims (Rule 42(1)(c) EPC).

9.8 For clarity the statement "spirit of invention" in the description on page 16, line 3 should be deleted (Art.84 EPC).

9.9 The attention of the applicant is drawn to the fact that the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed (Article 123(2) EPC).

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 03 79 6822

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

19-12-2007

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5045072 A	03-09-1991	US 5171232 A	15-12-1992
WO 9917827 A	15-04-1999	US 6077258 A	20-06-2000
US 5300048 A	05-04-1994	DE 69416451 D1	25-03-1999
		DE 69416451 T2	05-08-1999
		EP 0624380 A1	17-11-1994
		JP 6327758 A	29-11-1994
US 5814016 A	29-09-1998	NONE	
EP 0970715 A	12-01-2000	US 6126650 A	03-10-2000

European Patent Office

SUPPLEMENTARY EUROPEAN SEARCH REPORT

Application Number
EP 03 79 6822

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X Y	US 5 045 072 A (CASTILLO MIGUEL A [US] ET AL) 3 September 1991 (1991-09-03) * figure 1 * * column 3, lines 3-5,16,30-45 *	1,9 4-6,10, 11,14,16	INV. A61M1/00 A61M25/00 A61M25/01
Y	WO 99/17827 A (SCIMED LIFE SYSTEMS INC [US]) 15 April 1999 (1999-04-15) * page 4, lines 1-4,24-30 * * page 7, lines 4-6 *	4-6,10, 11,14,16	
A	US 5 300 048 A (DREWES JR DAVID A [US] ET AL) 5 April 1994 (1994-04-05) * the whole document * * figures 1,2 *	1-16	
A	US 5 814 016 A (VALLEY KIRSTEN L [US] ET AL) 29 September 1998 (1998-09-29) * abstract * * column 27, lines 23-31 *	1-16	TECHNICAL FIELDS SEARCHED (IPC)
A	EP 0 970 715 A (CORDIS CORP [US]) 12 January 2000 (2000-01-12) * abstract * * column 8 * * figure 1 *	1-16	A61M

The supplementary search report has been based on the last set of claims valid and available at the start of the search.

Place of search	Date of completion of the search	Examiner
Munich	19 December 2007	Türkavci, Levent

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C04)